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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,531	07/23/2003	Jacques Colinge	64176.000005	6658

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WASHINGTON, DC 20006-1109

EXAMINER

SKIBINSKY, ANNA

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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10/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/624,531

Applicant(s)

COLINGE ET AL.

Examiner

Anna Skibinsky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 25-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-24 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Applicants

Claims 12-24 and 59 are under examination.

Election/Restriction

Claims 1-11 and 25-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/09/2006.

Disclosure

This objection is withdrawn in view of amendments to the Disclosure filed 8/20/2007.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-19 and 21-24 and 59 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 12-19, 21-24 and 59 are drawn to a process for scoring a match of two peptides. The process for scoring the match involves the application of algorithms and computations of values such as the defining of an extended match E, generating a stochastic model with incorporates a probability distribution and finally scoring the

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extended match and, therefore, involves the application of a judicial exception.

Regarding inventions involving the application of a judicial exception, said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998), *AT&T Corp. v. Excel Communications Inc.* (CAFC 50 USPQ2d 1447 (1999))). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims recite a practical application; i.e. recites a useful, concrete, and tangible result. See MPEP 2106, in particular, Section IV, for an explanation of a concrete, tangible and useful result.

Claims 12-19, 21-24 and 59 do not recite a concrete, tangible AND useful result.

2. The final outputting step does not recite a concrete, tangible AND useful result. It is noted that the recited outputting step is tangible. However, the limitation directed to outputting encompasses the outputting of information that is related to (i.e. "based at least in part") the final scoring step but not necessarily inclusive of the scoring step. To be statutory, the claims must recite a result which is concrete, tangible AND useful. Currently, it is not clear what the result of the claimed steps is intended to be, therefore the result is not concrete. As such, the "outputting information based at least in part on the step of scoring the extended match E" does meet the limitation of being a tangible result but does not meet the criteria of being a concrete and useful result.
3. Furthermore, paragraphs 78 and 79 of the disclosure recite that L is a ratio and comprises "E" scores. Therefore, it appears that "E" is not a calculation of whether the

peptides match, it is just a theoretical score. However, L, which is calculated for E, or P seem to be the useful result which dictates the likelihood of a peptide match.

As the claims do not recite a physical transformation of matter OR a concrete, tangible and useful result, they are not directed to statutory subject matter.

Claim 20 is statutory because it recites an output of the "likelihood" which comprises a specific score and is the result of the method of claim 12, namely the determination of a match between peptides. Thus, the output of claim 20 is a result which is concrete, tangible and useful.

Response to Arguments

4. Applicant's arguments filed 3/21/07 have been fully considered but they are not persuasive.

5. Applicants argue (page 8, ¶3) that the requirement of being "useful, concrete, and tangible" is not relevant to the pending claims which are directed to a method of scoring a match between two peptides.

6. In response, the rejection is maintained because the final outputting step does not recite a concrete, tangible AND (i.e. as well as) useful result. Currently, the output step recites "outputting information based at least in part on the step of scoring the extended match E." Applicant's added step of outputting information has satisfied the criteria for a tangible result. However, it is not clear what the output is supposed to indicate with regard to the sequences being compared, which is the purpose of the method. Thus, the output step is neither useful in terms of the recited method nor is it

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concrete because it is unclear as to what exactly is being output. Thus, the requirement of a statutory result, wherein the claims must recite a result which is concrete, tangible AND useful, is not satisfied. For these reasons, the rejection is maintained.

7. Furthermore, Applicants argue that the claimed method steps are directed to "the output of the peptide match information," (page 11, ¶3).

8. In response, this is not the limitation that is recited in instant claim 12. The "match score" is recited in claim 20 and appears to be the "peptide match information" argued by applicants. It is again noted, as previously set forth and reiterated above, that claim 20 recites outputting a "match score," and thus claim 20 is deemed to be statutory. Claim 12 does not recite outputting a "match score" or "peptide match information" per se, but instead recites outputting information based at least **in part** on the step of scoring the extended match E," which for the reasons provided above does not meet the useful or concrete criteria for a statutory result of a method.

Claim Rejections - 35 USC § 112-2nd paragraph

This rejection is maintained from the previous Office Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-24 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 59 recite, "outputting information based at least in part on the step of scoring the extended match E." This is vague and indefinite because it is not clear what information is output and it is not clear what relationship is intended between claim elements by the limitation that one element is to be "based on" another. For the purpose of examination, the information output will be construed as being the scores of the extended match.

Response to Applicants

Applicants argue that the term "based on" does not render the claims vague and indefinite but only broad (Remarks, page 14 connecting paragraph and page 17).

In response, the instant limitation drawn to outputting information based at least in part on the step to scoring the extended match E renders the claim vague and indefinite because it is confusing as to what is actually being output. The method of claims 15 and 59 are drawn to scoring a match between two peptides. However the step of outputting encompasses any information "based at least in part" on the scoring of the peptides. It is confusing as to how said information is relevant to the claimed method and what this information might be. For these reasons this rejection is maintained.

With regard to the other 112,2nd issues, Applicants arguments (Remarks, pages 14, ¶2 to page 18) are persuasive and the rejections are hereby withdrawn.

Conclusion

No claims are allowed.

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1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anna Skibinsky, PhD

Raymond A. Moran
SPE, AO1631
10/22/07